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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	BVTP-P01-539	2183
28120	7590	12/29/2005		
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER WINAKUR, ERIC FRANK	
			ART UNIT	PAPER NUMBER
			3735	
DATE MAILED: 12/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/453,109	Applicant(s) PRAUSNITZ ET AL.	
	Examiner Eric F. Winakur	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,10-12,14-25,27-37,40,41 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 5,8,9,13,26,38,39,42 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims merely provide an intended use without properly setting forth further structural limitations.

Claim Rejections - 35 USC § 102

3. Claims 1, 2, 12, 14, 15, 18, 20, 22, 25, 27, 28, 31, 32, 36, 37, 40, 41, and 44 - 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (USPN 5,591,139 - previously cited). Lin et al. teach a microneedle fabricated from silicon wafers using IC processing methods for collecting and analyzing biological samples. The microneedle has a hollow shaft of length from 1 - 6 mm and width of approximately 80 μ m connected to an interface region (substrate) that includes a channel (collection chamber) for collecting and sensors for analyzing the fluid. Applicant's attention is drawn to Figures 1A, 2A, 6, 7, and the descriptions of column 3, line 19 - column 4, line 17 and column 9, line 34 - column 10, line 14. Further, resistors, micropumps, and microvalves may be incorporated into the microneedle (column 8, lines 26 - 54), which serve to selectively communicate/transport fluid to the collection area.

Claim Rejections - 35 USC § 103

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4. Claims 1 - 4, 6, 7, 10, 15, 27, 29 - 34, 36, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshihiko (JP 7 - 132119 - previously cited) in view of Lin et al. Yoshihiko teach a sampling device that is fabricated using semiconductor production techniques that includes an array of microneedles connected with a substrate and in fluid communication with a collection chamber (see Figures 1, 3; paragraphs 8, 9, 11, 14 - 16, 18, 20, and 21 of the translation previously submitted). The microneedles of Yoshihiko, as previously noted (see Remarks filed 26 December 2001; 17 June 2002), are 495 μm in length and 30 μm in width. Thus, Yoshihiko teach all of the limitations of the claimed invention except that the length of the microneedles is between 500 μm and 1 mm and that the device/method includes sensors in fluid communication with the microneedles. Lin et al., as described in paragraph 3 above, teach an alternate microneedle arrangement, that, like Yoshihiko is manufactured using semiconductor production techniques. Lin et al. teach that the microneedles can have lengths from 1 mm - 6 mm (determined by control of the semiconductor production techniques) and include sensors to allow real-time analysis of the collected fluids. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the microneedles of Yoshihiko to have lengths as given in Lin et al., since both microneedles are manufactured by semiconductor fabrication techniques and Lin et al. teach that microneedles of 1 mm length can be produced by these techniques, and further, to include sensors in the arrangement, since this allows real-time analysis of the collected fluids.

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5. Claims 1, 2, 11, 14 - 17, 19 - 21, 23, 24, 27, 28, 30 - 32, 35 - 37, 40, 41, and 44 - 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smart et al. in view of Lin et al. Smart et al. teach a microsampling device that is constructed using silicon microfabrication technique that includes a microneedle connected with a substrate, and a collection chamber with configurations for performing analysis of the analytes in the collected fluid, including glucose. Smart et al. teach that the microneedle has a width of 30 to 300 μm and a length of about 3 mm. Thus, Smart et al. teach all of the features of the claimed invention except for the particular length of the microneedle set forth in the claim. Lin et al., as described in paragraph 3 above, teach an alternate microneedle arrangement that, like Smart et al. is manufactured using semiconductor production techniques. Lin et al. teach that the microneedles can have lengths from 1 mm - 6 mm (determined by control of the semiconductor production techniques). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the microneedle of Smart to have lengths as given in Lin et al., since both microneedles are manufactured by semiconductor fabrication techniques and Lin et al. teach that microneedles of 1 mm length can be produced by these techniques. With regard to claim 11, as it is well known to use adhesive to retain medical sensors in contact with a subject during use of the sensor, it would have been obvious to provide the combination with adhesive to maintain the sensor in contact with a subject during a sampling.

Response to Arguments

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6. Applicant's arguments with respect to claims 1 - 4, 6, 7, 10 - 12, 14 - 25, 27 - 37, 40, 41, and 44 - 46 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a device that includes either: a collection chamber that is a syringe, has a one-way valve, or has a plurality of compartments; a means for controlling flow that is a fracturable or removable barrier; a microneedle having a hollow bore containing a material to modulate the flow of biological fluid; or wherein the microneedle comprises a metal, in combination with the other claimed elements.

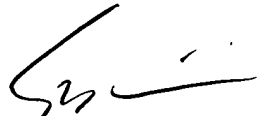
8. Claims 5, 8, 9, 13, 26, 38, 39, 42, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571/272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3735

23 December 2005